This equipment has been tested and found to comply with the limits for medical devices to IEC/EN 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. If this equipment does cause harmful interference to other devices, which can be verified by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device,
- Increase the separation between the affected equipment and the Controller,
- Connect the affected equipment to an outlet or circuit different from that to which the Controller is connected, or
- Consult the manufacturer or field service technician for help.

High frequency surgical unit with respect to electrical shock, fire and mechanical hazards only in accordance with: IEC/EN 60601-1/CAN/CSA C22.2 No. 601.1, and IEC/EN 60601-2-2.

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Introduction

The ArthroCare® Quantum™ (RF 12000) System is a bipolar, radiofrequency (RF) electrosurgical system designed for use in arthroscopic and orthopedic procedures. The System consists of the following components:

1) a bipolar radiofrequency Controller;

2) a reusable, non-sterile Power Cord;

3) a reusable, non-sterile Foot Control;

3a) a reusable, non-sterile wireless Foot Control (optional);

4) a reusable, non-sterile Patient Cable (optional); and

5) a disposable, sterile ArthroWand®.

The Quantum (RF 12000) Controller consists of four main components: the Main Board, Display Board with LCD Display, Medical Grade Power Supply and Front Panel Overlay. This manual will cover each of these components as well as provide the necessary information on calibrating, troubleshooting and performing routine maintenance for the Controller. Observe all warnings and precautions noted in this manual as well as in the Quantum (RF 12000) System User's Manual. Failure to do so may result in complications with the equipment, or safety hazards to the user or patient.

WARNING: All service must be performed by an Authorized Repair Facility. All service or repair questions should be directed to the ArthoCare Customer Service Department.

Functional Description of the Quantum System

The Quantum (RF 12000) Controller is designed to deliver RF energy to the electrode elements located at the distal end of the sterile single-use ArthroWands. Current flows from the active wand element to the integrated return Wand element, providing a localized energy field. The result of this arrangement is controlled energy delivery with minimal collateral tissue damage.

In the ablation mode, when sufficient energy is applied, the conductive solution is converted into a vapor layer (plasma) containing energized charged particles. When the high-energy charged particles come in contact with tissue, they cause its disintegration through molecular dissociation. This mode of operation results in relatively low treatment site temperatures when compared to conventional electrosurgical and monopolar RF systems, thus yielding limited collateral thermal damage to the surrounding untreated tissue.

The system can also function when a lower voltage is applied between the active and return electrode(s). In this case, the electrical field is below the threshold required to create a plasma layer and resistive tissue heating occurs. This mode is useful when a greater thermal effect is needed, i.e. for coagulation of blood vessel. The appropriate voltage setting will depend on the design of Wand used, tissue type, and desired tissue effect.

The Quantum (RF 12000) System provides two output connectors:

- The Cable Receptacle with the tan ring will accept the reusable Patient Cable (27 pin) with a disposable sterile Wand, making it compatible with the ArthroCare System 2000, or Integrated Cable Wand (ICW) with gray mating end.
- The Cable Receptacle with the black ring delivers higher power and will accept ICW with black mating end.

A single digit LED output display on the front panel of the Controller indicates the ablation voltage level settings. The table below shows relations between the open circuit output voltage and LED display in ablation and coagulation modes. In coagulation mode, the LED display shows “C”. The Quantum (RF 12000) Controller has a fixed coagulation voltage.

Display	Output voltage at tan receptacle (Vrms ± 10%)	Output voltage at black receptacle (Vrms ±10%)
0	0	0
1	100	100
2	126	126
3	154	154
4	180	180
5	207	207
6	234	234
7	260	260
8	287	287
9	314	314
10	NA	320
Coag 0	0	0
Coag 1	65	65
Coag 2	100	100

Board Level Description

The Quantum (RF 12000) Controller consists of four main components: Main Board, Display Board with LCD Display, Medical Grade Power Supply and the Front Panel Overlay. This section will describe in detail the function of each of these components.

Main Board:

- Provides primary power supply and patient isolation
- Generates a regulated power output of 70-330 Vrms (± 10%) at 100khz.
- Supports the system microcontroller (MCU) that sets the system clock, controls the peripheral components (Front Panel Overlay, Display, Sound, Foot Control, etc.), identifies high power mode and sets the default and maximum value for the type of Wand that is connected.
- Over temperature sensing circuitry
- Safety alarm circuitry

Display Board with LCD Display:

- Provides interface to the LCD Display.
- Provides LED indicators for Foot Control pedal, Wand, coagulation and alarm.
- Provides interface to Front Panel Overlay

Medical Grade Power Supply:

- Generates a regulated 12 VDC power output to supply the control circuitry

Front Panel Overlay:

- Houses the Up and Down arrow keys as well as the ablation indicator (Coblation Logo).

Main Board

The Main Board produces the 70-320 Vrms (±10%) at 100kHz signal that drives the electrodes at the distal end of the ArthroWands. The nominal Raw + 320 VDC is generated from the 120 VAC or 240 VAC line voltages using automatic line voltage switching (AVS) circuit built around U26. The circuit functions in two ways based on the AC input voltage. For 85 to 149 VAC, the circuit functions as a doubler. At 180 to 249 VAC, the circuit performs as a full-wave bridge rectifier.

The patient isolation barrier is created with the following components:

- T1, T2, T3, T4 and T5 current sensing transformers monitor current flowing through the four electrodes and integrated return respectively.
- U1 and U5 digital isolators provide isolation and interface to the Wand via the Handpiece & Cable Unit. These isolators along with the AD converter, U7 determine what type of Wand is connected, the position of the RF control switches and send this information to the MCU via the SPI interface.
- U3 temperature monitor measures the temperature of TC enabled Wands and sends this information to the MCU with the SPI interface.
- U13 digital isolator isolation to the RS-232 communication port.
- The AD converter, U7 determines if the high power ICW is connected to the Controller.
- U12 and U4 provide the isolated +12 V to the RS-232 and Wand recognition circuits.

The nominal Raw + VDC drives a phase-modulated full-bridge switch-mode regulator which is used to provide the necessary voltage output to the Wands. This circuit consists of four MOSFETs (Q14, Q15, Q16, and Q17) configured as a full bridge. Their phase of conduction or overlay is controlled by a phase shift resonant controller (U27). The MCU controls the on/off switching of this circuit by enabling the DC_EN which activates the “over current shutdown” (CS) on U27 via Q12. The output from this full bridge switch mode regulator (+MOD) is applied to the 100kHz inverter circuitry consisting of Q7, Q8, Q9, and Q10. The output from this inverter circuitry drives the output board via T6.

MCU - The MCU provides all necessary clock frequencies used throughout the system including the 100kHz sync signal. The MCU is also responsible for the control of the LCD display and indicator lights on the Display Board, the Up/Down arrow keys on the Front Panel Overlay, and the interface for the Foot Control. The MCU controls the different safety monitoring circuits in the system. This includes the output current limit circuit, over temperature sensing circuit, and detection of the Wand or Foot Control circuit. A variety of different audio tones are associated with these safety-monitoring circuits as well as with the normal operations of the system.

The following table describes each type of audio tone in detail. It includes the type of tone, description, and frequency of the tone.

Type	Description	Frequency
Ablation tone	Tone for normal operation	Continuous tone @ 620Hz
Set Point tone	Tone when setting voltage level	Single tone, 200ms @ 620Hz
Alarm tone	Tone for current limit	Alternating tone 200ms @ 620Hz and 1240Hz
Interlock tone	Tone when Foot Control pedal is pressed and either Wand or Patient Cable is not connected	Intermittent tone 200ms @2480 Hz
Coagulation tone	Tone when in Coagulation mode	Continuous tone @ 1240Hz

Medical Grade Power Supply

The Medical Grade Power Supply is an off-the-shelf SMPS that converts the 100-240 VAC supply voltage to a regulated 12 VDC output that is used to power the system control circuitry.

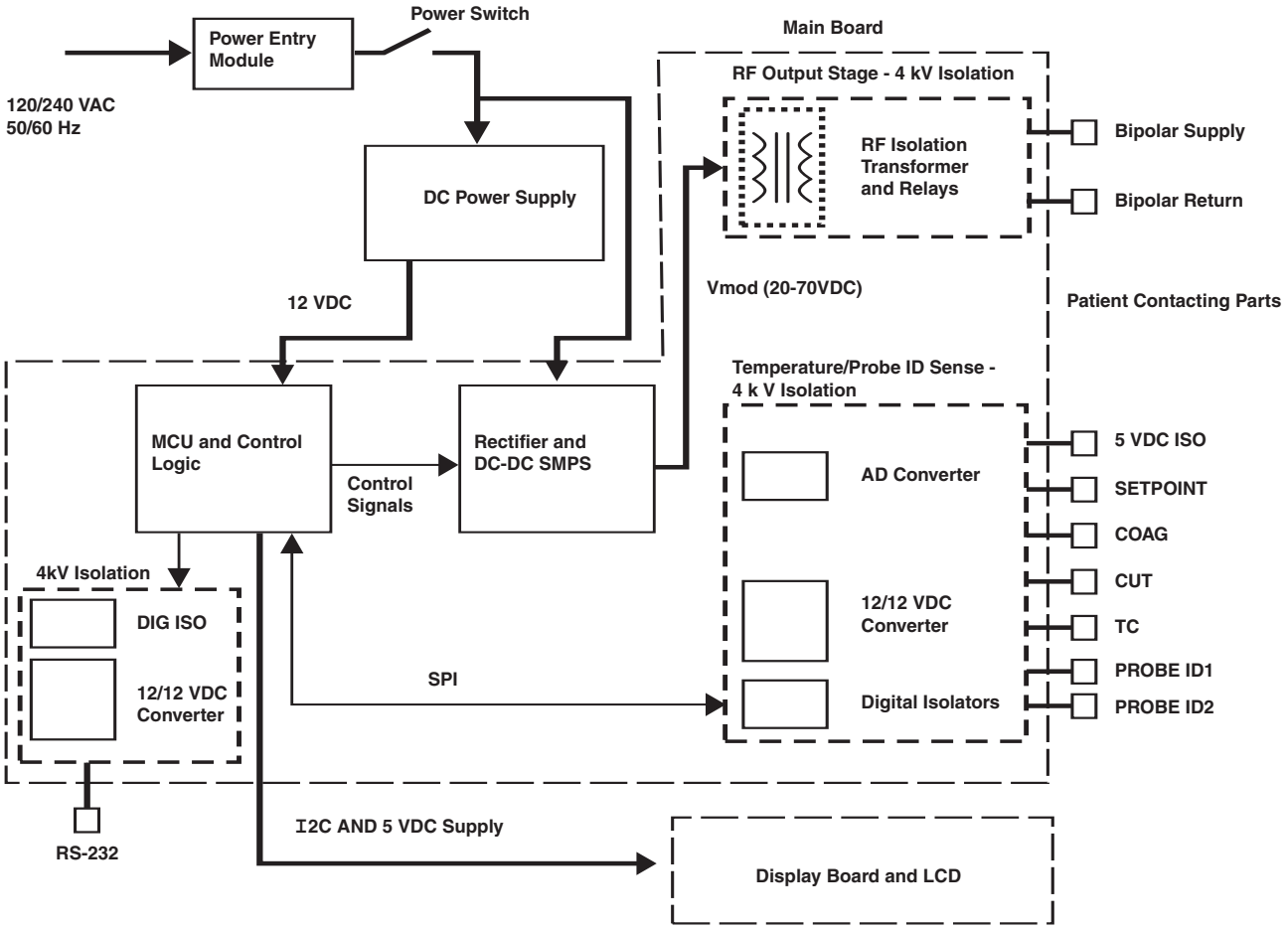
Display Board

The Display Board supports the LCD display and the indicator lights for the Foot Control, Wand, ablation, coagulation, and alarm. U1 is the port expander that provides the interface for Up and Down keys as well as the driving capability for the indicator lights for the Foot Control, Wand, ablation (Coblation Swirl Logo), coagulation and alarm. U5 provides the control voltages required to activate the LCD display.

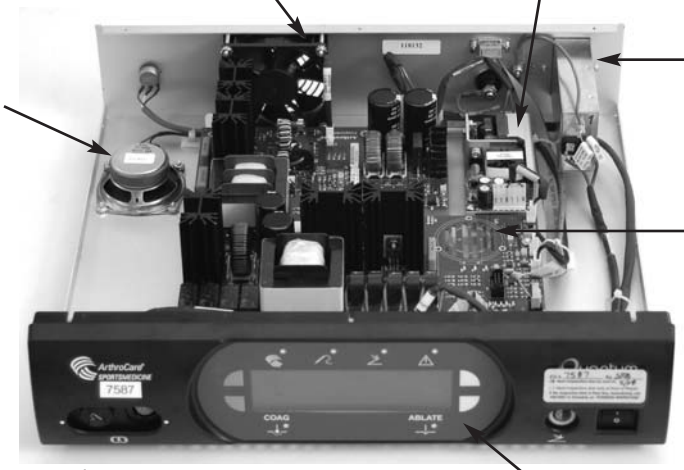
Front Panel Overlay

The Front Panel Overlay is a membrane panel that contains Up and Down arrow keys as well as the indicator lights.

Block Diagram for Quantum (RF12000) Controller



Inside view of the Quantum (RF 12000) Controller



Front View

Back View

System Maintenance and Troubleshooting Guide

Maintenance

The Quantum (RF 12000) Controller has been designed to function with minimal periodic maintenance, inspection, or internal system calibration. Cleaning of the outside surfaces of the Quantum (RF 12000) Controller is recommended in accordance with standard hospital practice. Periodic cleaning of the outside surfaces may be accomplished by using a nonabrasive cleaning detergent. Also, periodic cleaning and inspection of the Power Cord should be performed.

Troubleshooting Guide

This section is designed to aid the trained service technician/engineer in troubleshooting the Quantum (RF 12000) Controller. This section is only designed to troubleshoot to board level.

WARNING: Only trained qualified technicians should perform any repairs on the Quantum (RF 12000) System. Please contact the ArthroCare Corporation Customer Service Department before attempting any repairs on the Quantum (RF 12000) System.

Error Symptom	Corrective Action
Controller does not power up after the power switch is pressed.	1. Power Cord – Check that the Power Cord is plugged in properly to the Controller and into the appropriate outlet. If necessary, replace the Power Cord. 2. In-line fuses – Check that the in-line fuses, located in the rear of the instrument, are not blown. If they are blown, replace with the appropriate value fuse as per the User's Manual. 3. Main Board – Possible defective Main Board. Replace Main Board.
Green wand LED does not illuminate when a Wand with the Patient Cable or ICW is connected to the UUT.	1. Patient Cable – Check that the Patient Cable is connected correctly. 2. Wand – Possible Wand failure. Change Wand. 3. Patient Cable – Possible defective Patient Cable. Replace Patient Cable. 4. LED – Possible defective LED. Replace Overlay.

Troubleshooting Guide Cont'd

Error Symptom	Corrective Action
Green Foot Control LED does not illuminate.	1. Foot Control Connector – Check that the Foot Control is properly connected to the Controller. 2. Foot Control – Possible defective Foot Control. Replace Foot Control. 3. LED – Possible defective LED. Replace Overlay.
No Output	1. Foot Control and/or Patient Cable – Check all connections for the Foot Control, Patient Cable and Wand. 2. Wand – Possible Wand failure. Replace Wand. 3. Patient Cable – Possible Patient Cable failure. Replace Patient Cable. 4. Internal Harness Cable – Check that the main harness cable from the Output Board to the front panel Patient Cable connector is connected properly. 5. Main Board – Possible Main Board failure. Replace Main Board. 6. Voltage level set at zero – Make sure that the voltage level is set at a number ≥ 1.
Intermittent monotone alarm and the red LED illuminates when Wand is activated	1. Connections – Check all connections to the instrument. Make sure that the activated Wand with the Patient Cable or ICW are seated properly. 2. Wand – Possible Wand failure. Replace Wand. 3. Main Board – Possible Main Board failure. Replace Main Board.

Troubleshooting Guide Cont'd

Error Symptom	Corrective Action
Dual tone alarm and the red LED illuminates when Wand is activated.	1. Safety feature - The warning light of the Quantum (RF 12000) Controller is illuminated when the Wand is activated. The Quantum (RF 12000) Controller is designed to signal this type of alarm when the Wand is activated for an extended period of time without touching tissue. If this occurs, release Foot Control to reset the unit. 2. Wand – Possible Wand failure. Replace Wand. 3. Patient Cable – Possible Patient Cable failure. Replace Patient Cable.
Flashing display and indicator lights.	1. Main Board – Main Board failure. Replace Main Board.

Technical Specifications

Controller Functional Specifications

Input Voltage . . . . . .100-120/220-240 V~
Input Frequency 50/60Hz
RMS Current . . . . . .8 / 4 A
Maximum Output Power . . . . . .400W @ 217 Ω
Output Frequency 100kHz
Output Voltage Range . . . . . .0-320 Vrms @ 100kHz +/-10%

Environmental

Operating temperature range . . . . . .10 °C to 40 °C
Storage/Transportation temperature range . . . . . .-40 °C to 70 °C
Humidity range . . . . . .10% to 85% non-condensing
Pressure range . . . . . .500 to 1060 kPa

Dimensions and Weight

Controller:
Weight (max) . . . . . .< 5 kg (< 11 lbs)
Height . . . . . .10.2 cm (4.0 inches)
Width . . . . . .40.6 cm (16.0 inches)
Length . . . . . .40.9 cm (16.1 inches)

Controller Measuring Function

Temperature range . . . . . .20 to 60°C
Temperature resolution . . . . . .1°C
Calibrated accuracy . . . . . .±3°C

Safety

The Quantum (RF 12000) Controller meets the requirements of IEC/EN 60601-1, IEC/EN 60601-1-2, IEC/EN 60601-1-4, IEC/EN 60601-2-2, and CSA 22.2 No. 601.1.IEC/EN 60601-2-18. All units are tested to verify that they meet these requirements. These standards include, but are not limited to the following:

- Class Type — Class I, Type BF
- Leakage current, isolated patient connections — ≤ 100 µA at 100-120/220-240 V~, 50/60 Hz
- Leakage current, non-patient applied parts — ≤ 500 µA at 100-120/220-240 V~, 50/60 Hz
- Power cord resistance to chassis — ≤ 100 mΩ

Warnings, Precautions, and Adverse Events

The following is a list of Warnings and Precautions that apply to the general operation of the Quantum (RF 12000) System. For specific warnings and precautions, please refer to the Wand and the Patient Cable Instructions for Use.

⚠ Warnings

- The RF 12000 System is intended for use by healthcare professionals only. The RF 12000 System may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the RF 12000 System or shielding the location.
- Failure to follow all applicable instructions may result in serious surgical consequences.
- Explosion Hazard: The following substances will contribute to increased fire and explosion hazards in the operating room: flammable substances (such as alcohol-based skin prepping agents and tinctures), flammable anesthetics, naturally occurring flammable gases which may accumulate in body cavities such as the bowel, oxygen enriched atmospheres, and oxidizing agents such as nitrous oxide (N_2O) atmospheres.
- Fire Hazard: DO NOT place active accessories near or in contact with flammable materials (such as gauze or surgical drapes).
- Electrosurgical accessories, which are activated or hot from use, can cause a fire.
- Accessory tips may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of Wands outside the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrosurgical current carried through other instruments and conductive objects.
- Electrosurgical current may be generated in conductive objects by direct contact with the active Wand or by the active or return wand being in close proximity to a conductive object.
- If excessive heating or physical forces cause damage to the Wand tip, foreign body fragments may result, possibly requiring extended surgery for removal.
- DO NOT use the Quantum (RF 12000) System with non-conductive media (e.g. sterile water, dextrose, air, gas, glycine, etc.). Use only conductive media such as normal saline or Ringer's lactate.
- Electric Shock Hazard: DO NOT connect wet accessories to the Controller.
- Controller failure could result in an unintended increase in output power.

⚠ Precautions

- Prior to initial use, ensure that all package inserts, warnings, precautions, and Instructions for Use are read and understood.
- Safe and effective electrosurgery is dependent not only on equipment design, but also, to a large extent, on factors under the user's control. Only persons having adequate training should perform procedures with the Quantum (RF 12000) System.
- Consult medical literature relative to techniques, complications, and hazards prior to performance of any procedure.
- Evaluate patients for predisposing medical problems that may be aggravated by the stress of surgery.
- A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or Controller grounding is not compromised.
- When instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.

- When not in use, remove the Wand and place outside the operative field away from metallic objects. Wands should remain separated from other electrosurgical equipment to avoid inadvertent electrical coupling between devices. Otherwise, inadvertent activation may cause injury to patient and/or user or equipment damage.
- DO NOT wrap patient cables around metal objects. Wrapping cords around metal objects may induce currents that could lead to shocks, fires, or injury to the patient or surgical personnel.
- Use caution when using Wand tips to probe or manipulate tissue. Forceful contact between Wand tips and tissue or other instruments may result in damage to the instrument.
- DO NOT use the Wand as a lever to enlarge surgical site or gain access to tissue.
- DO NOT allow fluid to contact any electrical connectors on the Wands, Controller, or Cables during use.
- Maintain the lowest power setting necessary to achieve the desired tissue effect.
- Confirm proper activation of the Wand if a Controller Set Point is chosen outside of the selected, default settings.
- DO NOT allow patient contact with grounded metal objects, such as a surgical table frame or an instrument table, to avoid risk of shock. Grounding pads should not be used.
- DO NOT contact metal objects with an activated Wand.
- Observe fire precautions at all times. Sparking and heating associated with electrosurgery may be an ignition source.
- DO NOT use flammable agents for cleaning and disinfection of the Controller or Cables.
- As with other electrosurgical units, Wands and Cables can provide paths for high frequency current. Position the cables to avoid contact with the patient or other electrical leads.
- High frequency (HF) electrosurgical equipment such as the Quantum (RF 12000) System may adversely affect the operation of other electronic equipment.
- Electrodes should remain separated from other electrosurgical equipment to avoid inadvertent electrical coupling between devices.
- Monitoring electrodes should be positioned as far as possible from the surgical electrodes when HF surgical equipment and physiological monitoring equipment are used simultaneously on a patient. Monitoring electrodes are not recommended.
- Monitoring equipment incorporating high frequency current-limiting devices is recommended.
- DO NOT remove the cover of the Controller. Refer servicing to qualified personnel.
- DO NOT obstruct the exhaust fan (located at rear of Controller).
- DO NOT touch the Controller's fan and/or speaker while touching the patient.
- Before each use, check that all Controller indicator lights and audio signals are functional. Make sure that the power cable plug is properly connected to the Controller receptacle.
- To avoid risk of fire, only replace the Controller fuses with the same type and rating.
- Controller failure could result in an unintended increase in output power.
- The Quantum (RF 12000) System is designed to be operated exclusively as a unit. Only use accessories provided by ArthroCare Corporation.
- ArthroCare fully warrants the safety and efficacy of our devices when used as intended for indications for which they are approved. ArthroCare cannot verify the safety of single use Wands that have been reprocessed or reused.
- The Quantum System should not be used adjacent to or stacked with other equipment. If the system is used adjacent to or stacked with other equipment, the system should be verified that it is operating in its intended configuration.
- DO NOT use other ArthroCare Foot Controls. Use only the Foot Control provided with the Quantum System or the optional wireless Foot Control (P/N H4000-0X).
- When endoscopes are used with endoscopically-used accessories, the patient leakage currents may be additive.

Adverse Events

As a consequence of electrosurgery, damage to surrounding tissue through iatrogenic injury could occur.

Output Test Procedures

Output Test for the Quantum (RF 12000) Controller

The Quantum (RF 12000) System is designed to provide consistent output levels. The System is calibrated by clock crystals, voltage references and fixed resistors. There are NO internal adjustments in the instrument. Due to the integrated calibration methods utilized by the Quantum (RF 12000) System, no annual maintenance check is required. If necessary, an output test can be performed on the Quantum (RF 12000) System to verify that the output voltage levels are within the instrument's specifications.

WARNING: This output test procedure must be followed as stated using only the electronic equipment listed in this procedure. Extreme caution should be taken, as lethal high voltage is present during this test. Only qualified service engineers/technicians should perform this test. Any deviation from this procedure or failure to comply with the contents may result in complications with the equipment, and/or safety hazards to the user or patient, as well as, the warranty on the instrument to be voided.

The following equipment is required to perform the Output Test on the Quantum (RF 12000) System:

- Tektronix Digital scope Model TDS420 or equivalent
- Tektronix Differential probe Model P5200
- 250 Ω 250 W precision non-inductive load
- UltraVac™ ICW (ArthroCare P/N ASC5000-01) or equivalent (black receptacle)
- TurboVac™ ICW (ArthroCare P/N ASC1335-01) or equivalent (tan receptacle)

Step 1 – Setup the Tektronix Digital scope to the following settings

1. Sweep speed - 5μ sec per division
2. Voltage - 500 mV per division
3. Trigger - Normal Mode
4. Measure Mode - RMS and sample mode

Step 2 – Setup the Quantum (RF 12000) System as stated in the User's Manual. If using an ICW with black mating end, slide the sliding door to the left and connect the ICW to the back Cable Receptacle on the front of the Controller. If using an ICW with gray mating end, slide the sliding door to the right and connect the ICW to the tan Receptacle.

Step 3 – Clip the scope return to the neck of the Wand (unshielded outer metal part) and place in series the 250 Ω 250 W precision non-inductive load. Touch one end of the load to the Wand and attach the other end to the scope Wand tip.

Step 4 – Choose the set point level (1-9) and press the ablation activation pedal of the Foot Control. Multiply scope reading by a factor of 2 and verify the reading with the table below. Verify the coagulation output by pressing the coagulation pedal of the Foot Control.

Output voltage for Quantum (RF 12000) Controller in Ablation and Coagulation modes

Display	Output Range @ 100 kHz in Vrms	Typical voltage @ 100 kHz in Vrms
0	0	0
1	84-102	93
2	105-129	117
3	128-157	143
4	150-183	167
5	173-211	192
6	195-239	217
7	217-265	241
8	239-292	266
9	261-319	290
10	264-322	293
Coag 0	0	0
Coag 1	56-68	62
Coag 2	86-105	96

NOTE: If any of the voltage level readings are not within the above specifications, please contact the ArthroCare Corporation Customer Service Department immediately.

Output Test Using an Electrosurgical Analyzer

The Quantum (RF 12000) Controller power output (Wrms) can also be verified by using an Electrosurgical Analyzer (i.e. Dynatech 454).

WARNING: This output test procedure must be followed as stated using only the electronic equipment listed in this procedure. Extreme caution should be taken, as lethal high voltage is present during this test. Only qualified service engineers/technicians should perform this test. Any deviation from this procedure or failure to comply with the contents may result in complications with the equipment, and/or safety hazards to the user or patient, as well as, the warranty on the instrument to be voided.

The following equipment is required to perform the power output test on the Quantum (RF 12000) System:

• Electrosurgical Analyzer (Dynatech 454 or equivalent)

• Wand with Patient Cable, ICW or Adapter Cable (ArthroCare P/N 11617)

Step 1 – Set the Electrosurgical Analyzer to the following parameters:

1. Select Manual mode

2. Select Output Controller test

3. Set internal load to 250 Ω.

Step 2 – Set up the Quantum (RF 12000) System as stated in the User's Manual. Attach the Wand with Patient Cable to the Controller. When using the Adapter Cable, connect the Yellow lead to the "Active" input on the ESU and the Blue lead to the "Dispersive" or "Return" input on the ESU (see Figure 1). When using the Wand and Patient Cable, connect the "Active" input from the ESU to the tip of the Wand and the "Dispersive" or "Return" to the shield of the Wand.

Step 3 – Choose the Setpoint (1-9) and press the Ablation pedal of the Foot Control. Verify the readings with the table on the following page. Verify the coagulation output by pressing coagulation foot pedal.

NOTE: If any of the power level readings are not within the listed specifications, please contact ArthroCare Corporation Customer Service Department immediately.

Power Output for Quantum (RF 12000) Controller in Ablation and Coagulation modes

Display	Power Range @ 100 kHz in Wrms	Typical Power @ 100 kHz in Wrms
0	0	0
1	28-41	34
2	44-66	55
3	65-98	81
4	89-134	111
5	118-177	147
6	151-226	188
7	185-278	232
8	226-339	282
9	269-400	337
10	274-400	343
Coag 0	0	0
Coag 1	12-19	15
Coag 2	29-44	37

Customer Service

Warranty Information

The Quantum (RF 12000) Controller and Foot Control are warranted for one year and the warranty for the reusable Patient Cable extends for a period of 90 days from the date of shipment to the original purchaser. Any component of the System, which develops defects resulting from defective material or workmanship during these time periods will be replaced or repaired without charge.

Product Complaints

All questions or concerns related to the quality, reliability and/or durability of this product should be directed to ArthroCare Corporation Customer Service or an authorized ArthroCare representative. Please contact ArthoCare Corporation Customer Service or an authorized ArthroCare representative for a return merchandise authorization (RMA).

Manufacturer
ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA U.S.A.
Toll Free: (800) 797-6520 (Customer Service)
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ArthroCare Europe SE
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111 31Stockholm, Sweden
+46 8 546 172 00

Symbols Key

 Caution, Consult accompanying documents / Caution

 Manufacturer

 Authorized representative in the European Community

 Date of Manufacture

 Coagulation

 Ablation

 Ablation Set Point Adjustment

 Wand Connected

 Foot Control/Hand Control Connected

 Defibrillator-Proof Type BF Equipment

 Fuse Rating

 Non-Ionizing Radiation

 Equipotential Ground

 Tone Volume Control

 Fragile, Handle with Care

 Temperature Limitations

 Keep Dry

 Do not dispose in waste container

 Timer

 Humidity Range: 10% - 85% R.H., Non-condensing

 CE mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive (93/42/EEC).

Rx only CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

The ArthroCare Quantum System is covered by the following U.S. Patents: 5,697,909; 5,697,281; 5,697,536; 5,697,882; 5,683,366; 5,681,282; 5,766,153; 5,810,764; 5,843,019; 5,871,469. Additional patents issued and pending.

Rx only

CE
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P/N 21876 Rev. A
January 2008